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FDA hones Guidance on PCIDs

In the FDA's October 2011 Guidance, "Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anti-counterfeiting," the Agency defines a physical-chemical identifier (PCID) as "a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies and authenticates a drug product or dosage form." The Guidance also offers recommendations about incorporating PCIDs into solid oral dosage forms (SODFs). The recommendations address

- Design considerations;
- Supporting documentation to be submitted in NDAs and ANDAs;
- Supporting documentation to be submitted in post-approval; and
- Procedures for reporting or requesting approval as a post-approval change.

The draft version of this Guidance, issued in July 2009, was prompted by pharmaceutical manufacturers, who had been investigating new on-dose technologies to combat drug counterfeiting.

The comments on the draft guidance from industry were generally supportive of the FDA's actions, but there were also concerns, which the FDA took into account. For example, the draft Guidance included a section on using PCIDs in packaging, containers, and labeling. Commentators questioned the logic of including that information in a Guidance focused on dosage-level identifiers, and the final Guidance deleted that section entirely, making the final version a more focused document.

Commentators also emphasized the need for confidentiality about the existence and nature of the on-dose anti-counterfeiting measures so that counterfeiters couldn't obtain useful information. In response, the FDA pared its commentary related to PCIDs and product labeling and stated that "FDA does not intend to object if ingredients used as PCIDs are not included in the list of ingredients in a drug's labeling." The Agency also cited other applicable, existing regulations about product labeling requirements. While it remains to be seen how specific cases will be addressed, the final language on this point suggests that the FDA encourages novel anti-counterfeiting efforts and understands that pharmaceutical manufacturers need to use covert, on-dose countermeasures.

The final Guidance also clarifies the reporting categories and regulatory filings that are required when incorporating PCIDs into SODF drug products. In identifying three reporting categories, the FDA articulates applicable standards and gives instructive examples on how to garner less regulatory scrutiny. The FDA acknowledged that the amount of disclosure that using a PCID requires will "depend on its pharmacological and toxicological characteristics as well as the design of the SODF. For example, less disclosure information would be expected for a PCID, which is a permissible direct food additive, a food substance that is GRAS, or listed in the IIG, than for a novel PCID."

Clearly, the Guidance supports using PCIDs and on-dose authentication to fight counterfeiting. In a 2011 report, on drug diversion and counterfeiting cases from 2003 to 2008 [1], the FDA found that SODF drug products were the most common products involved in those types of cases, so the Guidance's focus on SODFs is appropriate. The report also highlighted examples of criminal drug schemes, including a number of drug diversion cases in which drug products were stolen or otherwise acquired in an unauthorized manner, then was reintroduced into the stream of commerce. Additionally, the FDA found several incidents where drug samples were sold to pharmacies and repackaged and sold at retail price. In schemes where packaging-level security measures were ineffective, dosage-level PCIDs could serve an important role, especially if they provided batch-specific information and other important data about the diverted drug product.

Conclusion

The FDA's final Guidance on PCIDs provides a strong framework for pharmaceutical manufacturers to begin implementing on-dose authentication measures in SODF drug products. The guidance also demonstrates that the FDA supports the pharma industry's use of on-dose technologies.

Finally, the Guidance provides a useful blueprint for other regulatory bodies to adopt so that manufacturers of drug products have international clarity when implementing on-dose authentication measures into their global supply chains. Pharmaceutical manufacturers should find encouragement in the PCID Guidance to explore on-dose authentication to fight counterfeit medicines. *T&C*

Reference

1. "FDA Conducts Preliminary Review of Agency's Diversion and Counterfeit Criminal Case Information." FDA Report. September 2011.

[*Editor's note:* To comment on the Back Page, visit www.tabletscapsules.com.]

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